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WEST-WARD PHARMACEUTICAL CORP.

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

MUTUAL PHARMACEUTICAL COMPANY, INC., ET AL,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., a Nevada Corporation; ET AL,

Defendants.

WEST-WARD PHARMACEUTICAL CORP.

Counterclaimant,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC., ET AL,

Counterdefendants.

Case No.: CV 09-05700 PA (RZx)

Related to: CV 09-05761 PA (RZx)

DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

(Declarations of James H. Nelems (2), Elizabeth Marro and Jason Grenfell-Gardner and Request for Judicial Notice filed concurrently)

The Honorable Percy Anderson

Date: TBA
Time: 1:30 p.m.
Place: Courtroom 15
312 N. Spring Street
Los Angeles, CA 90012

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I. Introduction

This case concerns the sale and marketing of a prescription drug called colchicine which, for the last 200 years, has been used to treat gout. Interestingly, most people share the common misconception that all prescription drugs are approved by the Food and Drug Administration ("FDA"), but this is not at all the case. Many commonly-used drugs -- such as Phenobarbital -- existed long before the FDA came into being and never received, nor ever have been required to obtain, FDA approval. The tablet form of colchicine is another one of those drugs. Nevertheless, recently, the Plaintiffs (for ease of reference, the Plaintiffs collectively will be referred to as "Mutual"), decided to obtain FDA approval for their colchicine tablets: the very same drug that they, and all the Defendants, had been selling for years without approval. The only difference after obtaining such approval is that Mutual now charges $485 per bottle instead of less than ten. *See* Declaration of Jason Grenfell-Gardner at ¶¶ 9-11 ("Grenfell-Gardner Decl.").

Now that its drug is FDA approved and it has raised the price fifty fold, Mutual seeks to prevent West-Ward and the other Defendants from continuing to sell unapproved colchicine – a rather unusually extreme remedy for a Lanham Act violation – despite the fact that they, and Mutual, have done so for years. *Id.* Obviously because the only party that has the power to order such a cessation is the FDA, and the FDA thus far has refused to act, Mutual has chosen to sue the Defendants for false advertising under the Lanham Act, contending that West-Ward makes (albeit only implicitly, not expressly) several false claims of FDA approval.

As the following discussion will demonstrate, there simply is no false advertising in this case, and even if there were, Mutual has completely failed to meet its burden of proving, not just that there is confusion in the marketplace, but that West-Ward's actions are the cause. Absent either of these essential elements,

Mutual's Lanham Act claim must fail. As a result, Mutual's request for preliminary injunctive relief should be denied.

II. Statement of Facts

Considering colchicine's two-century history, it is obvious that it, like numerous other drugs, existed long before creation of the FDA and the notion of FDA approval. In fact, it was not until 1962 that the FDA began requiring any drug that it deemed a "new drug" to secure approval of its safety and effectiveness. Essentially, all drugs are "new drugs" unless they are "Generally Recognized As Safe And Effective" ("GRASE"), or grandfathered in by being on the market prior to 1938. *See* 21 U.S.C. § 321(p); *U.S. v. Western Serum Co.*, 666 F.2d 335 (9th Cir. 1982).

To date, the FDA has not made this determination with regard to the tablet form of colchicine. Recently, however, in 2008, the FDA did evaluate injectible colchicine and determined that it was not necessarily safe and hence, not GRASE. *See* 73 Fed. Reg. 7565, 7566 (Feb. 8, 2008). Interestingly, in making this determination, the FDA expressly recognized that colchicine also was available in tablet form but specifically exempted it from the decision, noting that: "This notice does not affect the legal status of products containing colchicine in oral dosage forms, which FDA intends to address at a later date." *Id.*

To date, FDA still has not addressed the question of whether tablet colchicine must go through the approval process. Thus, while West-Ward's product has been registered with FDA for years, and all colchicine products are extensively regulated by FDA, there still is no express requirement that West-Ward seek FDA approval. *See* Declaration of Elizabeth Marro ("Marro Decl.") at ¶ 8. Nevertheless, both West-Ward and Mutual decided some years ago to work toward securing such approval for their colchicine products. Mutual recently completed the approval process and promptly raised the price for a bottle of 100 tablets from $9.06 to

$485.00. *See* Grenfell-Gardner Decl. at ¶¶ 9-11. To reap monopolistic profits from this excessive price increase, Mutual now seeks to bar the remaining distributors from the market.

Mutual's chosen tack to garner market exclusivity is this Lanham Act lawsuit. Here, while never claiming -- because it cannot truthfully do so -- that West-Ward ever expressly has represented falsely that it has FDA approval, Mutual urges that West-Ward makes three impliedly false representations: (1) that by selling colchicine tablets through various databases, pricing services, ordering services, and third-party internet sites, West-Ward is implying that its colchicine has FDA approval; (2) that West-Ward's package inserts convey a false impression that its product is safer than Mutual's; and (3) that West-Ward's product label falsely implies FDA approval and treatment of all types of gout.

Mutual offers very little proof in support of its case. It has introduced one expert affidavit that has no factual basis whatsoever and is, instead, simply the idle suppositions of a purported expert who repeatedly has flunked *Daubert* challenges in the past. It has submitted one "consumer survey" that proves nothing more than that the public labors under a pervasive misconception that all drugs are FDA approved, but is devoid of any evidence that West-Ward caused that omnipresent confusion. Finally, it mistakenly relies on the recent decision in *Mutual Pharmaceutical Co. v. Ivax Pharmaceuticals, Inc.*, 459 F. Supp. 2d 925 (C.D. Cal. 2006), a case from this district that has no precedential value whatsoever. That is, in *Ivax*, the defense focused solely on FDA preemption and completely failed to dispute Mutual's Lanham Act evidence, such as it was. Of course, even highly flawed evidence carries the day against no rebuttal evidence at all.

The present case is quite different. Not only does West-Ward challenge Mutual's substantive evidence of its Lanham Act claims, but it has a probative rebuttal survey that proves that West-Ward is ***not*** the cause of the market

confusion. Hence, as the following discussion will show, Mutual has no likelihood of success on the merits. Thus, no injunctive relief will lie.

III. Argument and Citation of Authority

I. MUTUAL'S UNCLEAN HANDS BAR ANY RELIEF

The doctrine of "unclean hands bars relief in Lanham Act cases when the plaintiff has engaged in precisely the same type of conduct about which it complains." *TrafficSchool.com, Inc. v. EDriver, Inc.*, 2008 WL 4000805, at *15 (C.D. Cal. Jun. 4, 2008). *See also Emco, Inc. v. Obst*, 2004 WL 1737355, at *4 (C.D. Cal. May 7, 2004) (holding that the unclean hands doctrine provides a defense to false advertising claims under the Lanham Act). Here, Mutual engaged in the ***exact*** same conduct of which it now complains – the distribution of unapproved colchicine tablets – for the past decade. While Mutual apparently ceased manufacturing its unapproved tablets prior to filing suit, the remaining inventory persists in the supply chain. *See* Grenfell-Gardner Decl. at ¶9 at Exh. B. Absent application of the unclean hands doctrine, there is a substantial likelihood that Mutual would enjoy a double recovery – by gaining monopoly status in the colchicine market, and from its own continued sale of unapproved colchicine tablets. *See Emco, Inc. v. Obst*, 2004 WL 1737355, at *5 (C.D. Cal. May 7, 2004) (denying injunctive relief in a false advertising claim where such relief would potentially result in a double recovery for plaintiff).

In view of the fact that Mutual literally engaged in the *exact* same conduct that it now decries, this is a textbook case for the application of the unclean hands doctrine. Thus, the Motion for Preliminary Injunction should be denied.

II. THE FACT THAT THE PRINCIPAL INJUNCTION FACTORS WEIGH IN WEST-WARD'S FAVOR WARRANTS THE DENIAL OF RELIEF

A preliminary injunction is "a harsh and extraordinary remedy … to be granted sparingly and only in cases where … the plaintiff has established a reasonable certainty of prevailing at trial." *Magellan Group Inv., LLC v. First Indigenous Depository Co., LLC*, 2005 WL 1629940, at *1 (N.D. Cal. July 8, 2005). To be entitled to injunctive relief, a plaintiff must show: (1) a probability of success on the merits; (2) that it would suffer irreparable injury if an injunction is denied; (3) that the balance of equities weighs in its favor;[1] and (4) that the injunction is in the public interest. *Stanley v. Univ. of S. Cal.*, 13 F.3d 1313, 1319 (9th Cir. 1994) (affirming denial of preliminary injunction). None of these factors weighs in Mutual's favor in this case.

III. MUTUAL HAS NO LIKELIHOOD OF SUCCESS

This is a Lanham Act false advertising case. 15 U.S.C. § 1125(a). In order to state a claim under the Lanham Act, at a minimum, a plaintiff must prove that the defendant issued false or misleading advertising about its or the plaintiff's product that deceived or confused consumers. *Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1052 (9th Cir. 2008) (emphasis supplied). As the following discussion will show, not only is there no false advertising, but there is no proof either that West-Ward caused any confusion that may exist.

IV. THERE IS NO "FALSE ADVERTISEMENT" IN THIS CASE

In the present action, Mutual urges three alternative bases for its Lanham Act claim: (1) that West-Ward listed or allowed colchicine tablets to be listed on prescription drug price lists and third-party databases (2) that West-Ward places an

[1] Except for the fact that absent survey evidence, there can be no irreparable harm, *see infra* §V, and thus Mutual has suffered none, neither the irreparable injury nor balance of harms factors are of particular moment in this case.

"Rx" symbol and the words "for treatment of gout on its label;" and (3) that West-Ward's labels and package inserts contain less information than Mutual's. As the following discussion will show, not one of these constitutes the requisite false advertising necessary for a Lanham Act claim.

As a threshold matter, there is no *advertising*, let alone *false* advertising, in this case. The Lanham Act applies only to "advertising, the purpose of which is to garner business advantage in the manner a traditional advertisement would." *Blaine Larsen Processing, Inc. v. Hapco Farms, Inc.*, 1999 WL 34809531, at *7 (D. Idaho June 16, 1999). *See Midwest Canvas Corp. v. Commonwealth Canvas, Inc.*, 2008 WL 162757 (N.D. Ill. Jan. 16, 2008) (an invoice is not advertising because it does not induce a purchase). Neither the third-party lists and databases nor Mutual's label and product inserts constitute advertising in the Lanham Act sense.

More than that, the requisite ***false advertising*** is completely absent here. Mutual's principal attack is based on the inclusion of West-Ward's colchicine in drug price lists and databases. This claim suffers in numerous respects.

First, the law requires that the false advertising in question emanate "from the defendant." *See Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *TrafficSchool.com, Inc. v. EDriver, Inc.*, 2008 WL 4000805, at *15 (C.D. Cal. Jun. 4, 2008); *Falcon Stainless, Inc. v. Rino Companies, Inc.*, 2008 WL 5179037 (C.D. Cal. Dec. 9, 2008). Mutual has no valid proof of this fact. Instead, it relies weakly on the mere supposition of its expert, James O'Donnell, that West-Ward simply must have tendered its drug to the databases. *See* O'Donnell Declaration at ¶ 16. Of course, O'Donnell has no personal knowledge of this fact and provided no foundation for his speculation.

O'Donnell's baseless conjecture cannot carry the day,[2] especially when contrasted with the testimony of West-Ward Sales and Marketing Vice President Jason Grenfell-Gardner that West-Ward never took any affirmative action to be included in the databases. Grenfell-Gardner Decl. at ¶¶. 6-7. Although Mutual notes that at least one site, buygenericdrugs.com, falsely represents that "all its drugs are FDA approved," this only means that buygenericdrugs.com may have some liability for its error, but that liability does not transfer to West-Ward when West-Ward did nothing to induce such statement. *See Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004) (noting that a gallery is not liable under the Lanham Act because "it did not make any of the alleged misrepresentations).

In any event, even if West-Ward had tendered the drug, the case law uniformly agrees that the mere placement of a drug on a database or price list does not constitute the requisite "false or misleading statement" necessary to make out a Lanham Act claim. *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (disallowing a Lanham Act claim based on implicit representations of FDA approval); *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 791 (W.D. Tex. 2001) ("false implications of FDA approval – as opposed to direct statements that a product was approved when it was not – are not actionable"); *Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 478 (D.N.J. 1998) (disallowing a Lanham Act where there was no false representation of FDA approval); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237, at *6 (D. Kan. Feb. 26, 1997) (denying Lanham Act claim based on a failure to

[2] O'Donnell has little credibility with the courts, *see Kunz v. DeFelice*, 538 F.3d 667, 676 (7th Cir. 2008) (finding O'Donnell earned his "Pharm.D. degree in only one year and with only one pharmacology class), and has been excluded as an expert on numerous occasions. *See, e.g., id; Agee v. Purdue Pharms., L.P.*, 242 Fed. Appx. 512, 514 (10th Cir. 2007) (excluding him for lack of any scientific basis); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1240 (11th Cir. 2005) (finding O'Donnell's opinions unsupported and methodology unacceptable).

disclose lack of FDA approval); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996).

For example, in *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), Mylan sued Matkari under the Lanham Act for falsely representing that it had FDA approval. Also in *Mylan*, just as here, Mylan grounded its case on the supposed implied representation inherent in simply placing a drug on the market. In noting Mylan's pleading failure in not alleging an express misrepresentation, the court held that "that fatal deficiency cannot be cured by contentions that the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow implies (falsely) that the drug had been 'properly approved by the FDA.' Such a theory is, quite simply, too great a stretch …." *Id.* at 1139.

Just as in *Mylan*, Mutual has failed to identify a single affirmative false representation that West-Ward has made. To conclude that the simple act of placing a product, or allowing it to be placed, on websites and drug lists simply goes too far. Hence, Mutual's Lanham Act claimed fails as well for want of a commercial misrepresentation.

Interestingly, the *Ivax* case, upon which Mutual relies so heavily, is not to the contrary. Although there, the court ultimately granted Mutual's requested preliminary injunction under analogous facts, it is important to note that the *Ivax* defendants ***never*** contested whether there was a false representation. Rather, the *Ivax* defendants chose not to refute Mutual's experts or surveys and focused their defense instead solely on FDA preemption of the Lanham Act claim. *See id.* at 939 (noting that preemption was "the only argument raised by defendants as to why Mutual lacks a probability of success on this claim"). Thus, *Ivax* has no precedential value in terms of whether an actionable misrepresentation occurred here.

Next, Mutual attacks West-Ward's placement of an Rx symbol and its inclusion of the "for treatment of gout" on its product label as misleading. This contention simply makes no sense. Since 1951, the Durham-Humphrey Amendment has required prescription medicines to carry the Rx designation. *See* 21 U.S.C. §353(b)(4)(A). Likewise, unless a medication indicates its use, it will be deemed illegally misbranded. *See* 21 U.S.C. §352(f); 21 C.F.R. § 201.5. Inclusion of statutorily-mandated information cannot be either false or misleading and thus cannot form the basis of a Lanham Act claim.

As a threshold matter, nothing contained in West-Ward's package inserts is either false or misleading, nor has Mutual contended as such. Mutual simply is unhappy with the fact that it chose to seek FDA approval and now is subject to the myriad regulations that FDA imposes. West-Ward has not yet finished the FDA approval process and, thus, need not supply all the same information in its package insert that Mutual has. Notably, however, the failure to include information on product labeling, even if the government so requires, cannot form the foundation of a Lanham Act claim in any event. *See IQ Prods. Co. v. Pennzoil Prods. Co.*, 305 F.3d 368, 372 (5th Cir. 2002) (holding label omissions ineligible to form the basis of a Lanham Act claim). Hence, Mutual has failed to prove the presence of false advertising in this case; an omission that alone warrants denial of the requested injunctive relief.

V. MUTUAL HAS FAILED TO DEMONSTRATE THAT WEST-WARD'S ACTIONS HAVE CAUSED ANY CONFUSION

A Lanham Act claim may be based on a misrepresentation that is false on its face or a representation that is literally true but likely confusing. *Castrol, Inc. v. Pennzoil*, 987 F.2d 939, 943 (3d Cir. 1993). When a claim is based on statements that are literally true but likely confusing, it is incumbent on the plaintiff to provide evidence of that confusion. *See Diamond Triumph Auto Glass, Inc. v. Safelite Glass*

Corp., 441 F. Supp. 2d 695, 708 (M.D. Pa. 2006) (it is not enough merely to argue how consumers might react; instead, the plaintiff must show how they actually did react). In short, the plaintiff must prove that a substantial portion of the market was misled. *See Johnson & Johnson-Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992) (a Lanham Act will claim will fail absent the threshold showing "that a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement").

The only acceptable vehicle for this proof is a consumer survey. *See New Sensor Corp. v. CE Distrib. LLC,* 303 F. Supp. 2d 304, 316 (E.D.N.Y. 2004) ("Where an advertisement is not literally false, but rather is ambiguous or implicitly false, a plaintiff can ***only*** establish a claim of false advertising through a survey.") (emphasis added). *See also Proctor & Gamble Co. v. Ultreo, Inc*., 574 F. Supp. 2d 339, 345 (S.D.N.Y. 2008) ("Where a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged commercials tend to mislead or confuse consumers."); *Walker & Zanger, Inc. v. Paragon Indus., Inc.*, 549 F. Supp. 2d 1168, 1182 (N.D. Cal. 2007) ("if an advertisement is not false on its face, … plaintiff must produce … market research or consumer surveys, showing exactly what message ordinary consumers perceived"); *Am. Home Prods. Corp. v. Proctor & Gamble Co.,* 871 F. Supp. 739, 760 (D.N.J. 1994) ("Because public reaction is the measure of a commercial's impact, an implied falsity claim must be proven in a false advertising case via the use of a consumer survey."). But not just any survey will do.

The case law is clear that in order to have evidentiary value, surveys must be properly designed and objectively conducted. They must filter out individuals whose responses may distort the results and ensure that the questions are not leading or suggestive. *Proctor & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339,

345-46 (S.D.N.Y. 2008) (quoting *Johnson & Johnson-Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 300 (2d Cir. 1992)). As West-Ward's survey expert, Jim Nelems, explained, Mutual's survey flunked all of these tests.

The only survey that Mutual has proffered is one by Joseph Matijow. Matijow's survey protocol deviated markedly from accepted survey methodology and the questions were structured to provoke the desired response. *See* Second Declaration of James H. Nelems ("Nelems Second Decl.") at ¶¶ 15-23. Moreover, Matijow never asked the question that is central to this case: why the pharmacists believed that colchicine was FDA approved. *Id.* at ¶ 31. Absent proof that pharmacists believe that colchicine is FDA approved because it appeared in databanks and price lists, Matijow's survey has no probative value in this case.

That is, a properly probative survey must show, not just that there is confusion, but that the defendant is the cause. *Hill's Pet Nutrition, Inc. v. Nutro Prods., Inc.*, 258 F. Supp. 2d 1197, 1211 (D. Kan. 2003) (finding the plaintiff's survey deficient where it failed to reveal the cause of the confusion); *Pfizer, Inc. v. Miles, Inc.*, 868 F. Supp 437, 447 (D. Conn. 1994) (finding no customer confusion where the survey failed to show that the defendant was the cause). Mutual has failed in this quest. Not only has it not provided surveys for some of its claims, but the survey that it did provide is qualitatively deficient and completely fails to prove that West-Ward *caused* the public's widespread erroneous belief.

First, just as it did in the *Ivax* case, here Mutual completely has ignored its burden of proving that the label or product insert causes confusion because its survey is silent with regard to these items. Instead, Mutual has introduced only the testimony of a single Rheumatologist who opined that "[o]mitting the complete adverse event warnings from their labels makes Defendants' products appear safer to the public than they actually are." Rothschild Declaration at ¶ 19. As the *Ivax*

court noted, "[s]uch speculative beliefs are insufficient to establish irreparable harm." *Ivax*, 459 F. Supp. at 945. The same insufficiency exists here. Thus, even if the label or product inserts were advertising and/or were false, which West-Ward disputes, Mutual's failure to demonstrate market confusion vitiates Mutual's claim in any event.

As to the websites and databanks, Matijow's survey reveals only what already is obvious: that most pharmacists mistakenly believe that all prescription drugs are FDA approved. Because the Matijow survey sheds no light on the basis for that belief and completely fails to prove that West-Ward's actions or inactions are the root of the confusion, Mutual's reliance on Matijow's survey results is clearly misplaced.

For example, in *American Home Products Corp. v. Proctor & Gamble Co.*, 871 F. Supp. 739, 760 (D.N.J. 1994), the manufacturer of a nonprescription analgesic brought a false advertising claim against a competitor for commercials it deemed both literally and implicitly false. Although AHP provided a survey to demonstrate the impact of the allegedly-offending advertisements on the consuming public, its expert "conceded that the survey's built-in control mechanism could not in fact control for any preconceptions regarding analgesics that the survey population may have possessed …." *Id*. at 762. In denying AHP's motion for preliminary injunction, the court criticized the survey because it was "unable to discern if [the] survey results are attributable to the advertisement or are instead attributable to consumers being bombarded with years of OTC advertising from which their pre- or misconceptions of these products have developed." *Id.* Thus, because the survey failed to show that Proctor & Gamble's actions actually caused confusion as opposed to there being simply preexisting confusion in the marketplace, it had no evidentiary value.

Matijow's survey suffers from this very flaw. It fails to prove that West-

Ward caused the confusion about which Mutual complains.

Ignoring this glaring deficiency in its proof, Mutual simply assumes that because it has proffered the same survey that carried the day in the *Ivax* case, the same result should obtain here. This assumption rests on a faulty base. That is, because the *Ivax* defendants grounded their defense solely in a preemption argument, they did not contest or rebut Matijow's flawed survey or submit their own in defense. This left the court with no choice but to "assume[] these surveys are reliable," *id*. at 946, because they were "something which defendants have not challenged in this case …." *Id.*

This is not at all the situation here. Here, not only has West-Ward submitted evidence that Matijow's survey is flawed from the start, it conducted its own thorough survey that proved what Matijow's did not: there is no evidence that West-Ward caused any confusion in the drug market. Because causation is a crucial element of a Lanham Act claim, Mutual's claim must fail.

That is, despite its obvious bias and myriad questioning flaws, Matijow's survey still completely failed to demonstrate what is essential to Mutual's success in this case: that West-Ward's listing of its colchicine tablets on price lists and databases causes customer confusion. *See* Nelems Second Decl. at ¶¶ 29-32. To the contrary, all the Matijow survey demonstrates is precisely what commentators and even the FDA itself acknowledge: most people in this country – not just pharmacists – labor under the erroneous belief that *all* drugs – not just branded ones, not just generics and not just prescription – are FDA approved. *Id.* at 29. That is, even the FDA widely has acknowledged that the public simply assumes that all drugs are FDA approved. Former FDA Commissioner, Dr. Andrew von Eschenbach, noted that "consumers wrongly ***assume*** that these widely marketed and available drugs are approved and have been found to be safe and effective by

the FDA ."[3] Likewise, the Oprah show felt the need to do a program on the issue of unapproved drugs because "[p]eople tend to ***assume*** that if a drug is available in the U.S., it's safe and it works."[4]

Doctors' years of medical training apparently do not save them from embracing the same misconception. As the President of the American Medical Association stated: "I think most doctors, maybe all doctors, ***assume*** that if a medication is on the market, it has been approved by the FDA …."[5] "Pharmacists would appear to be no better informed …. A recent survey showed more than nine out of 10 retail pharmacists didn't know they could be dispensing drugs not yet approved by the FDA." *Id.*

The most interesting thing about each of these quotes is their use of the word, "assume." Not a single speaker went on to say that the assumption was grounded in placement of unapproved drugs on price lists but rather the simple fact that a drug is sold. There is similarly nothing whatsoever in the Matijow survey to indicate how this erroneous belief in FDA approval came about or whether it emanates from any particular source. One thing that is certain, however, is that the mere fact that ***colchicine*** is on price lists and websites did not create the widespread misconception that ***all*** drugs are FDA approved. *See* First Declaration of James H. Nelems ("Nelems First Decl.") at ¶ 12.

West-Ward's own pharmacist survey affirms this fact. While confirming the existence of the pervasive belief that drugs are FDA approved, it takes the step that Matijow's survey neglected: it asks the question why. That is, the Nelems survey blatantly asked pharmacists: "How do you know that colchicine is FDA approved?" Nelems First Decl. at Exh. A. In response, not a single pharmacist cited a computer database as the source of his or her belief. Instead, 27% stated

[3] http://www.fda.gov/AboutFDA/WhatWeDo/History/ThisWeek/ucm117836.htm
[4] http://www.oprah.com/article/omagazine/200906-omag-fda-approved-drugs
[5] http://www.cnn.com/2007/HEALTH/conditions/09/26/unapproved.drugs/index.html

that it was because it is a prescription drug; 27% stated that it simply was because it is on the market; 25% stated that they had heard of Mutual's recent approval; 11% stated that it was used for gout; 9% said it is dispensed by the pharmacist; 8% stated that the product has been on the market for a long time;[6] 6% had never even heard that it was not approved; and 5% stated that the product was grandfathered in. *Id.* *Not a single survey participant attributed his or her belief to the inclusion of West-Ward's product on a database or website.*

In summary, whatever the cause of the erroneous perception actually is, it is clear what it is not: it is not anything that West-Ward has done. Hence, Mutual has wholly failed as well to prove the requisite causation necessary to make out a Lanham Act claim. There can be no doubt that its request for a Preliminary Injunction should be denied.

VI. THE PUBLIC INTEREST IN HAVING ACCESS TO LOW COST ALTERNATIVES TO MUTUAL'S SUDDENLY EXORBITANT DRUG TIPS STRONGLY IN FAVOR OF DENYING INJUNCTIVE RELIEF

The grant of injunctive relief would disserve the public interest in each of three different ways in this case. First, Mutual argues that an injunction "clearly serves the public interest." Plainly, this is not so. Considering that an injunction would force pharmacists toward Mutual's higher priced product, the only thing that is "clear" is that Mutual seeks to compel consumers to pay $485.00 for a bottle of pills that is otherwise available for less than ten. Grenfell-Gardner Decl. at ¶ 11. *See The Upjohn Co. v. Am. Home Prods. Corp.*, 1996 WL 33322175, at *25 (W.D. Mich. April 5, 1996) ("the public has an interest in low cost prescription medications generally").

[6] Interestingly, the court in *Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc.*, 174 F.3d 1227 (11th Cir. 1999) (withdrawn) echoed its belief that the sheer amount of time that various products have been on the market likely contributes to the public's erroneous belief that a given drug is FDA approved. The court deemed it quite reasonable for the public to "assume that any medication freely available and prescribed by their doctor has been proven safe and effective to the satisfaction of the FDA," *id.*, when it has been on the market for decades.

Next, the case law admonishes courts to be cautious in interfering with the competitive process. *See J & M Turner, Inc. v. Applied Bolting Tech. Prods., Inc.*, 1997 WL 83766, at *19 (E.D. Pa. Feb. 24, 1997). "Absent extraordinary circumstances, the public interest is best served by allowing businesses to compete freely without court involvement." Moreover, "[t]he public interest is clearly not served by a court's prohibition of advertising that is not clearly false or misleading." *Id.* Because Mutual has failed to identify a single false representation that West-Ward has made, the public interest militates against judicial interference in the competitive realm.

Finally, Mutual's public interest assertions regarding the dangers associated with West-Ward's product are baseless and offer similarly little justification for injunctive relief. Not only has West-Ward manufactured more than a billion colchicine tablets in its history yet had only four reportable events in the past 17 years, *see* Marro Decl. at ¶¶ 6; 10, but the FDA itself acknowledged that tablet colchicine provides a "margin of safety that often prevents serious and fatal overdoses …." 73 Fed. Reg. 7565, 7566 (Feb. 8, 2008).

While Mutual touts FDA's report of 169 deaths "associated with" oral colchicine, these deaths have been experienced over the 200-year lifespan of the drug. What is more, "associated with" does not mean "caused by." Rather, FDA encourages the reporting of adverse events if they are even suspected of being associated with an FDA-regulated drug. In any event, this statistic stands in stark contrast to the 56,000 emergency room visits, 2,600 hospitalizations, and estimated 450 deaths *per year* from using acetaminophen (the active ingredient in Tylenol). L. Highleyman & A. Franciscus, The Liver: Acetaminophen and Your Liver.[7] Thus, it would clearly disserve the public interest to limit access to reasonably-priced forms of this safe and effective drug.

[7] http://www.hcvadvocate.org/hepatitis/factsheets_pdf/ Acetominophen.pdf

VII. MUTUAL HAS NO LIKELIHOOD OF SUCCESS ON ITS STATE LAW CLAIMS EITHER

Mutual takes the position that if it prevails on its Lanham Act false advertising claim, it will succeed on its state law claims as well. Not surprisingly, the courts of this Circuit have consistently held that these state law claims "are substantially congruent to claims made under the Lanham Act." *Switchmusic.com, Inc. v. U.S. Music Corp.*, 416 F. Supp. 2d 812, 827 (C.D. Cal. 2006). Mutual provides no additional facts or legal arguments in support of its state law claims. Therefore, because Mutual is not likely to succeed on its Lanham Act claims – as demonstrated in this Brief – Mutual is also not likely to succeed on its state law claims. *See CKE Restaurant v. Jack in the Box, Inc.*, 494 F. Supp. 2d 1139, 1147 (C.D. Cal. 2007) ("Because Plaintiffs do not raise any additional argument and neither party argues that the state claims require consideration of different legal standards, the Court finds that Plaintiffs have not established a likelihood of prevailing on their state claims"). As such, the Mutual's inclusion of three state law claims has no bearing on the present motion.

VIII. THE FDA HAS PRIMARY JURISDICTION OVER THIS CASE

West-Ward incorporates by reference the arguments of the other Defendants regarding the primary jurisdiction doctrine and its applicability to this case. By seeking to remove West-Ward's colchicine from the market, Mutual essentially is seeking to have this Court determine that colchicine is a "new drug" in need of FDA approval. As the Ninth Circuit has made clear, as a result of "the FDA's expertise in resolving technical and scientific questions, *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1376 (9th Cir. 1983), when determining "whether a drug sought to be marketed constitutes a "new drug" subject to the provisions of the Food, Drug and Cosmetic Act, the FDA has primary jurisdiction." *Id.* FDA has not determined that oral colchicine tablets are a "new drug" or that they require

approval to be lawfully marketed. Yet that is precisely what Mutual asks this Court to assume. Until FDA makes this determination, this matter is not even ripe for adjudication.

IV. Conclusion

For the myriad reasons espoused above, including the fact that West-Ward has not published any false advertising that has caused confusion in the marketplace, West-Ward respectfully requests that the Motion for Preliminary Injunction be denied.

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